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The objective of this study is to develop informational messages for women with breast cancer about managing chemotherapy related symptoms, integrating them with the TLC monitoring system and then evaluate the usefulness of the informational messages in reducing symptom severity and distress in patients receiving a cycle of chemotherapy for breast cancer. The aims of the study are:

1. To test the feasibility of implementing a computer-based telephone communication system (TLC) to provide informational messages about self care strategies for breast cancer patients during a cycle of chemotherapy.
2. To assess subject satisfaction, level of acceptability and the degree of difficulty in using the system from the patient's perspective.
3. To explore if subjects receiving informational messages about self care strategies have less symptom severity and symptom distress than subjects not receiving the informational messages.

We will employ an experimental design with random assignment to TLC monitoring or TLC monitoring and informational messages. Both groups of subjects will be instructed to call the TLC system on a daily basis during chemotherapy. Descriptive statistics will be needed to analyze aims 1 and 2. For exploratory aim 3, *t-tests* will be utilized to test the differences in mean score on symptom severity and symptom distress.

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INTRODUCTION

Today most cancer treatment is provided on an outpatient basis. While this is both economical and preferable for most cancer patients, it presents logistical difficulties for providing adequate management of the side effects that result from these treatments. Cancer chemotherapy causes a variety of side effects that occur within hours to two or three weeks after treatment. Since patients are at home during this time, they must be the ones to identify and manage them, determining on their own what self-care activities might be helpful in managing problems and determining when they need to contact the clinic for further assistance. Communication and coordination of symptom relief treatment between the cancer care team and the patient may be improved through utilization of emerging computer-based telecommunication technology. Employing telecommunication technology may help monitor side effect patterns and provide a method to coach patients about self care strategies at the time they are experiencing symptoms (Greist, 1997; Friedman, Stollerman, Mahoney, Rozenblyum 1997).

Computers possess infinite patience and perfect recall. This enables them to accurately substitute for repetitious tasks including those in health care that are routine and non-interpretive (Markson, Friedman, Jette, Kazis, 1992). A major application is in chronic disease management that allows monitoring of patients' health status and transmits this clinical information from patients in their home to their health care providers. For cancer patients receiving chemotherapy, computer-based telecommunications would allow remote assessment and home monitoring of subjective symptoms, functional status and ability to continue daily activities. Basic screening questions can be asked with patients responding with a numerical response using the touch tone keys on the telephone. If symptoms are present, the computer is programmed to ask further assessment questions. This technology can also be programmed to educate and counsel patients about appropriate actions to take based on the specific profile of symptoms they are experiencing.

Once such computer-based telecommunication system is Telephone Linked Care (TLC) that was developed by a medical informatics team led by Robert Friedman, M.D. at Boston Medical Center (Friedman et al., 1997). TLC has been tested for both health behavior management and chronic disease management for over ten years. For health behaviors, TLC has been utilized to monitor and counsel patients who are participating in smoking cessation, diet modification, and exercise programs (Dutton, Posner, Smigelski, Friedman, 1995; Cullinane, Hyppolite, Zastawney, Friedman, 1994; Friedman, 1998). For chronic disease monitoring and counseling, TLC has been tested include asthma, hypertension, angina, congestive heart failure and diabetes (Friedman, Kazis, Jette, Smith, Stollerman, Torgerson, Carey, 1996; Markson, et al., 1992). We are the first group to adapt the TLC technology to the cancer setting.

The concept award has permitted us to develop and soon test the counseling component of the TLC system for patients receiving chemotherapy for breast cancer.

Objectives

The objective of this pilot study is to develop informational messages about managing 8 common symptoms (nausea/vomiting, trouble sleeping, fatigue, feeling blue, feeling nervous, fever, sore mouth and pain), integrating them with the TLC symptom monitoring system and then evaluate the usefulness of the informational messages in reducing symptom severity and distress in patients receiving a cycle of chemotherapy for breast cancer. The specific aims of the study are:

4. To test the feasibility of implementing a computer-based telephone communication system (TLC) to provide informational messages about self care strategies for breast cancer patients during a cycle of chemotherapy.
5. To assess subject satisfaction, level of acceptability and the degree of difficulty in using the informational messages from the patient's perspective.
6. To explore if subjects receiving informational messages about self care strategies have less symptom severity and symptom distress than subjects not receiving the informational messages. This will assist us in projecting an effect size for a further clinical trial of the system.

BODY

Patient/ Site Selection

Patients, 18 years of age or older, who are beginning a cycle of breast cancer chemotherapy at the Huntsman Cancer Institute clinic or Boston Medical Center oncology clinic will be invited to participate in the study. Subject recruitment will include all eligible patients on the days that research assistants are in the clinics and will continue until sixty subjects have been entered into the study. Subjects must have daily access to a touch tone telephone, understand and speak English and not have any physical or mental conditions that would prevent them from participating. Patients will be randomized to receive TLC monitoring only (control group) or TLC monitoring *and informational messages* (intervention group).

Design

In this pilot study, we will employ an experimental design with random assignment to TLC monitoring or TLC monitoring and informational messages. Both groups of subjects will be instructed to call the TLC system on a daily basis beginning 24 hours after starting a cycle of chemotherapy and continuing until the start of the next cycle or for 30 days, whichever is less. At the end of the call in time period, the subject will be interviewed either by telephone or during a clinic visit to gather satisfaction and acceptability data about TLC and to obtain suggestions for improvement.

Study Procedures

The initial phase of the study was to develop the informational self care messages for the 8 symptoms. We utilized an evidence-based approach and national guidelines wherever possible. We have completed this phase.

Currently we are in the second phase with the messages being converted into a dialogue script for programming. The Boston Informatics Team is preparing the design specifications. The integration of the dialogue into the system entails four steps: computer specification of the conversation logic, design of the system's database, entering the dialogue content and voice recording of the dialogue.

Once the subject calls the 1-800 number and enters their PIN, TLC greets patient and then proceeds to ask them a series of screening questions regarding their symptom pattern over the previous 24 hours. For symptoms that are present in moderate (5 on a scale of 0 to 10), the TLC system then goes back and asks more detailed questions. Based on these assessment data, informational messages will be triggered to respond to moderate or severe symptoms. For example if the subject indicates they have moderate pain from mouth sores, indicates they have prescribed pain medication but have only taken once in 24 hours, as one information strategy, TLC will remind the subject that patient medication should be taken on a scheduled basis.

Phase three will be the conduct of the pilot study. Patients will be evaluated in the two clinics and if they meet study criteria they will be invited to participate. After signing the consent (see appendix), the subject will receive a personal identification number (PIN) and be instructed on how to use the TLC system. A demonstration will be provided. Demographic data will also be collected (see appendix for demographic sheet). The subject will then be instructed to call into a 1-800 number daily, enter their PIN and proceed to answer the TLC questions (see appendix for initial monitoring script). The subject will be reminded with each call to directly speak with their physician and their clinic if the have symptoms or other concerns. Subjects will continue to call into the system daily until they begin a new cycle of chemotherapy or 30days has elapsed, whichever comes first. At that time the subject will be contacted for a post-TLC interview either by telephone or while in the clinic whichever is more convenient. The post-TLC interview will assess subject satisfaction with TLC and suggestions for improvement.

Statistical Methods, Data Analysis and Interpretation

As a pilot, feasibility study descriptive statistics will be needed to analyze aims 1 and 2. Demographic data will be used to describe the sample with frequency distributions and simple descriptive statistics such as means, ranges and standard deviations. We will also examine the symptom pattern reports for each subject and determine if the answers provided to the more detailed assessment questions provided useful clinical data. Average length of calls and the range of call lengths will be calculated. Also we will compute the adherence rate with daily phone calls and tabulate the number and percentage of calls initiated but not successfully completed. We will analyze the post-TLC subject interview with frequency distributions for all categorical items. For continuous level data, means, modes, ranges and standard deviations will also be determined. We will tabulate suggestions received from the post-TLC subject interviews to determine what improvements are needed in the script. Content analysis will be used to analyze the data obtained from the qualitative, open-ended questions. For exploratory aim three, *t-tests* will be utilized to test the differences in mean score on symptom severity and symptom distress.
As a pilot study no elaborate sample size calculation was attempted. Rather, 60 subjects were determined to be a realistic number and financially feasible to evaluate the monitoring and the informational message components of the TLC system for breast cancer patients receiving chemotherapy.

KEY RESEARCH ACCOMPLISHMENTS

Per Article 4 (5) c of the Grant Agreement the University of Utah will extend the performance period to August 31, 2002. The project is in the second phase of three phases. Phase 1 of the project was the development of the complete self care strategies intervention script for the computer-based telephone-linked care system. Phase 2 is the computer programming of the script and debugging process. We also are obtaining the final sign off on the lengthy human subject approval process of the Department of Defense. Phase 3 is the pilot testing phase with women undergoing adjuvant chemotherapy for breast cancer. We expect to begin Phase 3, participant recruitment in March 2002 and finish recruitment May 31, 2002. Data Analysis will proceed June through August 2002.

REPORTABLE OUTCOMES

The grant is currently in phase 2 of three phases. The intervention script is being computer programmed and debugged at present.

CONCLUSIONS

No conclusions to date (see above).

REFERENCES

Dutton, J., Posner, B., Smigelski, C., Friedman, R. (1995) Lowering of total serum cholesterol through use of DietAid: a telecommunication system for dietary counseling. *Ann Beh Med* 17 (suppl.):S088.

Cullinane, P., Hyppolite, K., Zastawney, A., Friedman, R. (1994) Telephone Linked Communication: activity counseling and tracking for older patients. *J Gen Int Med* 9 (suppl 2): 86a.

Friedman, R. (1998) Automated telephone conversation to assess health behavior and deliver behavioral interventions. *Journal of Medical Systems* 22(2): 95-102.

Friedman, R., Kazia, L., Jette, A., Smith, M., Stollerman, J., Torgerson, J., Carey, K. (1996) A telecommunications system for monitoring and counseling patients with hypertension. *American Journal of Hypertension* 9:285-292.

Friedman, R., Stollerman, J., Mahoney, D., Rozenblyum (1997) The virtual visit: using telecommunications technology to take care of patients. *Journal of the American Informatics Association* 4(6):413-425.

Greist, J., Jefferson, J., Wenzil, K., Kobal, K., Baily, T., Katzelnick, D., Hagerson, S., Dottl, S. (1997) The telephone assessment: efficient patient monitoring and clinician feedback. *M.D. Computing* 14(5): 382-387.

Markson, L., Friedman, R., Jette, A., Kazis, L. (1992) Computers as clinician extenders: monitoring chronic illness in elderly patients. *International Journal of Technology and Aging* 5 (2): 153-165.